

REMARKS

The pending Office Action addresses claims 1-35, rejecting claims 1-27. Claims 28-35 are withdrawn from consideration.

Amendments to the Claims

Applicant amends independent claim 1 to specify that the sensor is “embedded in” a distal portion of the catheter. Support for this amendment can be found throughout the specification, for example, at page 6, lines 24-26. No new matter is added.

Claim Objections

“About”

The Examiner objects to claims 8 and 22 as being indefinite for using the term “about.” Specifically, the Examiner argues that the term “about” “is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.” Applicant respectfully disagrees.

The Federal Circuit has made it clear that the term “about” is not indefinite and that a person having ordinary skill in the art will readily understand the meaning of this term. For example, in *Chemical Separation Technology Inc. v. United States*, 51 Fed. Cl. 771, 782-783 (Fed. Cir. 2002), the Federal Circuit held that the use of the language “a pH of about 5” “does not render the claim here indefinite, as illustrated by the fact that the Federal Circuit has, on several occasions, construed the scope of a range of “about” numbers in determining whether a patent was infringed.” The Court cited various cases that have held that claims employing the term “about” are definite. *See, e.g., Zoltek Corp.*, 48 Fed. Cl. at 300; *see also Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995) (“the meaning of the word ‘about’ is dependent on the facts of a case, the nature of the invention, and the knowledge imparted by the totality of the earlier disclosure to those skilled in the art”); *Modine Mfg. Co. v. United States Int’l Trade Comm’n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996) (“Although it is rarely feasible to attach a precise limit to ‘about’ the usage can usually be understood in light of the technology embodied in the invention.”), *cert. denied*, 518 U.S. 1005 (1996); *W.L. Gore & Assocs.*,

Inc. v. Garlock, Inc., 721 F.2d 1540, 1557 (Fed. Cir. 1983) (descriptive term “about,” when used to describe ranges in a patent, does not render a claim indefinite), *cert. denied*, 469 U.S. 851 (1984); *CPC International Inc. v. Archer Daniels Midland Co.*, 831 F. Supp. 1091, 1110 (D. Del. 1993) (“In the context of determining an appropriate tip speed for a particular vessel and agitator, a person skilled in the art would not find the term ‘about 600 cm/sec’ to be unclear.”), *aff’d*, 31 F.3d 1176 (Fed. Cir. 1994), *cert. denied*, 513 U.S. 1184, 130 L. Ed. 2d 1129, 115 S. Ct. 1176 (1995); *Zoltek Corp. v. United States*, 48 Fed. Cl. 290, 300 (Fed. Cl. 2000) (“The Court does not agree with Defendant's contention that a precise limit must always be attached to the term ‘about.’”); *Syntex (U.S.A.), Inc. v. Paragon Optical Inc.*, 1987 U.S. Dist. LEXIS 14544, 7 U.S.P.Q.2D (BNA) 1001, 1038 (D. Ariz. 1987) (“‘About’ is not broad or arbitrary but rather is a flexible term with a meaning similar to ‘approximately.’”).

In all of the claims objected to in the present application, the term “about” precedes a numerical quantity (i.e., one half of the length of the catheter) and is included so as to avoid unnecessarily strict numerical boundaries. In all of these claims, a person of ordinary skill in the art would understand the proper limitations when examined in the context of this technology. Therefore, the term “about” is not indefinite and withdrawal of the objection is respectfully requested.

“Substantially”

The Examiner also objects to claims 9 and 23 as being indefinite for using the term “substantially.” Again, the Examiner argues that the term is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree. Applicant respectfully disagrees.

As with the term “about,” the Federal Circuit has long held that the use of the term “substantially” in claims is not indefinite, even where the term is not defined in the specification. In *Verve, LLC v. Crane Cams, Inc.* 311 F.3d 1116 (Fed. Cir. 2002), the Federal Circuit stated:

While reference to intrinsic evidence is primary in interpreting claims, the criterion is the meaning of words as they would be understood by persons in the field of the invention. Patent documents are written for persons familiar with the relevant field; the patentee is not required to

include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial and treatise for the generalist, instead of a concise statement for persons in the field. Thus resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention.

Id. at 1119-1120. The Court further explained that “[e]xpressions such as ‘substantially’ are used . . . in order to accommodate the minor variations that may be appropriate to secure the invention . . . and indeed may be necessary in order to provide the inventor with the benefit of his invention.” *Id.* at 1120. The Court thus held that the language “substantially constant wall thickness” was not indefinite.

Applicant also refers the Examiner to *Ecolab Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001), in which the Court likewise held that the term “substantially” is not indefinite. The Court stated that “like the term ‘about,’ the term ‘substantially’ is a descriptive term commonly used in patent claims to ‘avoid a strict numerical boundary to the specified parameter,’” quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995). In *Liquid Dynamics Corp. v. Vaughn Co., Inc.*, 355 F.3d 1361 (Fed. Cir. 2004), the Court again held that the language a “substantial helical flow path” is not indefinite, and they construed the term in this case as a meaningful modifier implying “approximate” rather than “perfect.”

Accordingly, it is well established that the term “substantially” is not indefinite as used in claims, and therefore reconsideration and withdrawal of this objection is respectfully requested.

Rejection Pursuant to 35 U.S.C. §102

U.S. Patent 5,291,896 to Fonger

The Examiner rejects claims 1-11, 13, and 15-27 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,291,896 to Fonger et al. (“Fonger”). Applicant respectfully disagrees.

Independent claim 1, as amended, recites an implantable fluid management device having an elongate catheter, a sensor embedded in a distal portion of the catheter, and at least one wire having a

distal end coupled to the sensor and a proximal end that is adapted to mate to an external component for powering and/or communicating with the sensor.

Fonger does not teach or even suggest a sensor that is embedded in a distal portion of a catheter, as required by independent claim 1. Fonger discloses a cardiac output probe assembly having a chest tube (12) which carries an output probe (14) therein. As shown in Figures 1 and 4 of Fonger, the probe (14) has a transducing head (22) that *extends from* a distal end of the tube (12) and is adapted to be implanted in an exterior surface (62) of a pulmonary artery or aorta vessel (64). (Fonger column 3, lines 46-49; column 4, lines 50-52). The Examiner asserts that the tube (12) includes a distally disposed sensor (14). However, Fonger merely teaches *extending* the transducing head (22) from the distal end of the catheter or *retaining* the transducing head (22) within the tube (12). The transducing head (22) is not embedded in a distal portion of the tube (12). Fonger thus fails to teach or suggest a sensor that is embedded in a distal portion of a catheter, as required by independent claim 1. Accordingly, independent claim 1, as well as claims 2-17 which depend directly or indirectly therefrom, distinguish over Fonger and represent allowable subject matter.

Independent claim 18, as amended, recites an implantable fluid management device having an elongate catheter, a sensor disposed at a distal portion of the catheter, at least one wire extending through the catheter, and a slit extending through an outer wall of the catheter. The at least one wire has a distal end that is coupled to a sensor and a proximal end that is mated to an external antenna.

Fonger does not teach or even suggest at least one wire mated to an external antenna, as required by independent claim 18. The Examiner asserts that the electrical connector (26) positioned at the proximal end (28) of the probe (14) is an antenna. However, an antenna is generally regarded by those skilled in the art as a device that can communicate wirelessly, e.g., by transmitting and receiving radio waves. As explained by Fonger, the electrical connector (26) is merely a plug that connects the probe to external circuitry and instrumentation – it does not communicate wirelessly with any other devices. (Fonger column 3, lines 49-54). Accordingly, the electrical connector (26) is not an antenna, and independent claim 18, as well as claims 19-27 which depend therefrom, distinguish over Fonger and represent allowable subject matter.

Rejection Pursuant to 35 U.S.C. §103

Fonger and Quackenbush

The Examiner rejects claims 12 and 14 pursuant to 35 U.S.C. §103(a) as being obvious over Fonger in view of U.S. Patent 5,104,398 to Quackenbush (“Quackenbush”). The Examiner argues that Fonger teaches the claimed invention except for “the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and wherein the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary catheter.” The Examiner relies on Quackenbush to teach these features, arguing that it would have been obvious to modify the device of Fonger in view of Quackenbush to arrive at the claimed invention. Applicant respectfully disagrees.

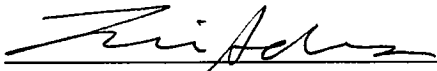
Claims 12 and 14 depend from independent claim 1. As explained above, Fonger fails to teach or even suggest a sensor that is embedded in a distal portion of a catheter, as required by claim 1. Quackenbush does not remedy the deficiencies of Fonger because Quackenbush also fails to disclose a sensor embedded in a distal portion of a catheter. Accordingly, independent claim 1, as well as claims 2-17 which depend directly or indirectly therefrom, distinguish over Fonger and Quackenbush, taken alone or combined, and represent allowable subject matter.

Conclusion

In conclusion, Applicant submits that claims 1-27 are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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